

# LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740  
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October 10, 2006

**HAND DELIVERED**

Document Processing Desk (**AMEND**)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington VA 22202

**ATTENTION:**       **Velma Noble**  
                          **Product Manager, Team 31**

**SUBJECT:**           **Lonza, Inc.**  
                          **Lonza Disinfectant Wipes (EPA Reg. No. 6836-313)**  
                          **Application for Pesticide Amendment, Fast Track**

Dear Ms. Noble:

As agent for Lonza, Inc., we are submitting an application to amend the Lonza Disinfectant Wipes label. The purpose of this amendment is to add numerous marketing claims and make a few minor labeling modifications.

Enclosed, please find the following documents to support this amendment:

- a) Application for Pesticide Amendment;
- b) One (1) copy of the proposed product label with changes highlighted, and;
- c) Five (5) copies of the proposed product label.

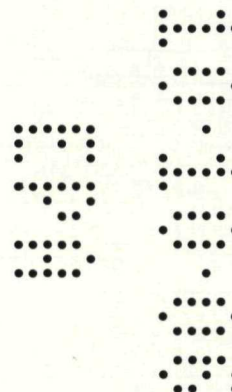
If you have any questions about the enclosed submission, please contact me at 202-393-3903 x16.

Sincerely,

*Christina M. Swick*

Christina M. Swick  
Agent for,  
Lonza, Inc

cc: Robert Sloan (Lonza, Inc.)





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 8 2007

Ms. Christina Swick  
Agent for Lonza, Inc.  
Lewis and Harrison  
122 C Street, NW  
Suite 740  
Washington, DC 20001

Subject: Lonza Disinfecting Wipes  
EPA Registration No.: 6836-313  
Amendment Date: October 10, 2006  
EPA Receipt Date: October 10, 2006

Dear Ms. Swick,

The amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Marketing claims
- Alternate Formulations #2 and #3

**Conditions**

Revise the label as follows:

1) Delete the following claims because it implies heightened efficacy:

- New Extra Power for your tough jobs (p.2)
- Convenience of a wipe, Power of (Mr. Clean) (cloth) (p.2)
- Power Tool (p.4)
- Powerful Mr. Clean Formula (p.4)
- Magic of Mr. Clean (p.4)

2) Any claims that the product will prevent or mitigate any diseases or infections constitute a drug claim; therefore, you must delete the following claims:

- Prevents the spread of 99.9% of bacteria (p.3)
- Reduce spread of illness causing bacteria (p.4)
- Hygenic (p.6)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

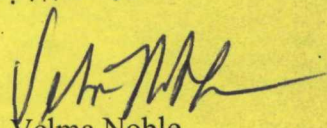
## General Comments

The Confidential Statements of Formulas for alternate formulations 2 and 3 dated April 14, 2006 are acceptable.

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



# LONZA DISINFECTANT WIPES

One Step Cleaner / Disinfectant / Deodorizer

FRESH / (SUMMER) CITRUS/ FLORAL/ MINT/ PINE / LEMON / WOODY/  
LIME / MELON/ CLEAN / WATERFALL / (ULTIMATE) ORANGE / (SPARKLING) APPLE /  
INVIGORATING BREEZE / SPRING GARDEN / LAVENDER (FRESH) / GRAPEFRUIT  
FRAGRANCE / (ULTRA FRESH) SCENT / SCENTED

## Active Ingredients:

Octyl decyl dimethyl ammonium chloride .....	0.069%
Dioctyl dimethyl ammonium chloride .....	0.028%
Didecyl dimethyl ammonium chloride .....	0.042%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride.....	0.093%
Other Ingredients:.....	99.768%
Total .....	*100.000%

\* Includes weight of absorbent wipe.

ACCEPTED  
WITH COMMENTS  
in EPA Letter Dated:  
JAN 8 2007  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.  
6836-313

KEEP OUT OF REACH OF CHILDREN

## CAUTION

See (left) (side) (right) (back) panel for Precautionary Statements and First Aid

Manufactured by:  
Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401

EPA Reg. No. 6836-313

EPA Est. No. (as indicated on container)

Net Contents: insert # (premoistened) (towelettes) (wipes) (disinfecting) (antibacterial) (cleaning) (wet) (multi-purpose) (touch-up) (pre-moistened cloths) (sheets)

(Note to reviewer: The following is considered optional marketing language :)

(for the first six months only)

New  
New larger (bigger)-sized wipe  
Introducing  
New Larger Size  
New Top  
New (thick) (textured) wipe  
New easy to dispense  
New EZ (to start lid) (start package) (Grab Lid)  
New Easy (Start Lid) (Start Package) (Grab Lid)  
Introducing new  
Tough Cleaning at your Fingertips!  
New (Convenient) (Amazing) Package  
New easy-glide dispensing top  
New tougher wipe for tougher cleaning  
[REDACTED]  
New tougher wipe for your tough(er) jobs

Bonus Size  
Travel (Size) (pack)  
Refill (size) (pack) (Refill for Lonza Disinfectant  
Wipes container (tub)

Ready to Use  
Premoistened  
Cleans  
Disinfects  
Deodorizes  
Antibacterial  
Cleaning

For Homes, Institutional and Industrial Use

(text for pop up containers only)

Pop up  
Pop and go  
Pop and Clean

Convenient (size)  
Value Size

- (After use), just toss wipe away (in trash)(in garbage).
- (All) (Multi-purpose) kitchen (everyday) (daily) (touch-up) (cleaning)
- (Finally) a wipe that cleans and disinfects
- (Premoistened) (wet) disinfecting (textured) (antibacterial) (wipes) (towelettes) (cloths)
- (Quick) (easy) way to (clean and) disinfect (in one step)
- (With a) (fresh) (clean) (citrus) (lemon) fragrance
- (With proven) Antibacterial Action
- Multi-purpose
- Multi-surface
- All around the house (disinfecting) (cleaning formula)
- Ammonia Free (formula)
- An effective way to clean and deodorize against odor-causing bacteria.
- Antibacterial Formula
- Better (package) (dispensing)
- Bleach Free (formula)
- Breakthrough package
- (A) Clean you can trust
- Clean with just a wipe or a touch up
- Cleaning just got a whole lot easier
- Cleans and disinfects in one (easy) step
- Cleans and disinfects (without scratching) (surfaces)
- Cleans things you never thought a wipe could
- Cleans (tough messes) (tough grease) (baked on grease) (sticky messes)
- Cleans what you can't see
- Cloth-like (textured) (strong)
- (Cloth-like texture) (Textured) for scrubbing power
- Cloths (Wipes) quickly remove dirt, spots and smudges
- Convenience of a wipe, [REDACTED] (a cloth)
- Convenient

*(optional Marketing language)*

- (Convenient) (Hassle-free) (One-hand) dispensing
- Cuts through (tough) (dirt) (stains) (grime) (soils) (dried on stains) (dried on soils)
- Cuts (tough) grease, kills bacteria
- Disinfecting (Disinfectant) (cleaner) (cleaning wipes) (wipes) (cloths)
- Disinfects (as it cleans) (and scrubs in one easy step)
- Disinfects while cleaning (up) stubborn messes
- Dispenses better
- Does not contain (chlorine) bleach or ammonia.
- Dual action-cleans up stubborn messes while it disinfects
- Easy (dispensing) (Glide Lid)
- Easy-glide dispensing top
- (Easy) (EZ) start
- Easy dispense (lid) (package)
- Easy to (open) (thread) (access lid) (dispense)
- Easy to use
- Effective in the presence of 5% serum contamination
- Effectively disinfects common household surfaces
- Extra Power for your tough cleaning jobs
- Extra Power wipe for cleaning extra tough (jobs) (messes)
- Fast drying; leaves no dull or sticky residue
- For a cleaner, fresher (home) (house), great for (all around) the (house) (home) (kitchen) (bath)
- For a Powerful Clean
- For (light touch ups) (quick clean-ups) (in one easy step)
- For household surfaces (all around the house) indoor and outdoor
- For the quick touch ups, try Lonza Disinfectant Wipes
- For use (at home), (away from home), (in public places) (on the go)
- For when a regular wipe (just) can't get the job done
- Freshens (as you clean)
- Fresh, clean scent
- Gets up stuck-on messes (so you don't have to get on hands and knees)
- Great for cleaning around the toilet
- Handles daily clean-ups with no need for additional sprays, sponges or buckets.
- Heavy (light) duty (jobs)
- Helps you finish (cleaning) fast (quickly)
- (Just like a tissue box) (Tissue box dispensing)
- Just (pull) (pop) wipe and toss.
- Kills bacteria (while it cleans)
- Kills common household bacteria
- (Kills) (Eliminates) (Removes) (Destroys) ( ) 99.9% of bacteria
- (Kills) (Eliminates) (Removes) (Destroys) ( ) 99.9% of bacteria, leaves surfaces (clean and) disinfected
- Leaves a clean, fresh scent
- Leaves (no residue) (a streak free shine)
- Leaves surfaces clean and disinfected
- Leaves surfaces in the (kitchen) (house) (home) hygienic
- Leaves your (bathroom) (kitchen) fresh and clean
- Light, clean scent
- (Long lasting) (lasts a long time) (goes further) (last longer)
- Makes (your job) (cleaning) (easier) (easy)
- More cleaning in one wipe
- No harsh scent

*(optional Marketing language)*

- No (mixing) (spraying) (mess) (and / or fuss) (no muss)
- No (more) (pinched fingers) (rips) (tears)
- No rinsing required
- No sprays, no sponges, no mess
- Non-abrasive
- Non-scratch(ing)
- Non-scratching
- Now cleaning is (faster) (easier) than (ever) (before)
- One at a time (dispensing, like a tissue box)
- One step (clean) (cleaning)
- One wipe at a time dispensing
- One wipe goes a long way
- Package breakthrough
- Patent pending
- Phosphate free
- Picks up more messes than other wipes
- Portable
- [REDACTED]
- Powers through (tough messes) (the dirt) (the grime)
- [REDACTED]
- Quick easy clean-ups.
- Reduce (risk of cross contamination) [REDACTED] (on hard non-porous surfaces)
- Removes the grime to give you more time (alt: Removes the grime so you have more time)
- Saves steps
- Saves Time
- Specially designed package that easily dispenses one at a time
- Specially formulated for use in the (kitchen) (bathroom)
- (Strong) (Thick) wipe
- Strong wipe for Heavy Duty cleaning
- Strong wipe for tougher (jobs) (messes)
- The convenient way to disinfect your household surfaces
- The convenient way to keep your home looking "just cleaned"
- The Magic of Mr. Clean
- The smart (way to) clean (and disinfect)
- The wipe that disinfects while it cleans (up (stubborn) (stuck-on) messes)
- The wipe that is (strong) (durable) (thick) (heavy) enough to scrub (and) (clean)
- The wipe to use when you don't have much time
- These (wipes) (towelettes) (cloths) will not harm (most) surfaces.
- Thick (wipe), cloth-like texture
- Thicker
- Thicker than an ordinary wipe
- This product contains no (phosphates or) phosphorous (compounds).
- Touch Up
- Tough cleaning (made easy) (made easier) (at your fingertips)
- Tough enough to do the bigger cleaning jobs.
- (Tough) (Thick) wipe for tough cleaning
- Tough(er) wipe for tough(er) cleaning (jobs)
- Two in one action (cleans and disinfects in one easy step)
- Use (daily) to clean bathroom soils such as soap, soap scum, toothpaste, hair spray, hair gel, cosmetics, shaving cream, hand or body lotion.
- Will not scratch

*(optional Marketing language)*

- Wipes are good for quick touchups
- With a cloth-like 3D texture
- With extra cleaning power (wipes) (sheets) (cloths)
- With (extra) scrubbing power
- With extra strength (wipes) (sheets) (cloths)
- Worry free (disinfecting) (cleaning)
- No more need to get on your hands and knees to (scrub) (or clean) stubborn spots.
- (Antimicrobial) (antibacterial) (disinfecting) and scrubbing power all in one
- (Textured cloth) gets up stubborn stuck on messes
- 3 (steps) in 1- wipes, scrubs and disinfects (so you finish faster)
- Cleans faster because the (scrubbies) (texture) removes (stubborn) (stuck on) (dirt) (messes)
- Dual (action) (purpose) (scrubs) wipes
- No more need to get on your hands and knees to (scrub) (or clean) stubborn spots.
- Scrub-N-Wipe(s)
- Scrubs like no other (wipe)
- Scrubs like no other (wipe)
- Textured (cloths) (towelettes) clean floors faster (and easier)
- Textured (Wipe) (cloth) (towelette) (for tough jobs)
- Powers through tough messes
- Powers through tough messes all over the house
- Thicker, cloth-like feel for tough messes
- Thicker than the leading brands
- Easier dispensing than the leading brands
- Fewer rips, bunches, and snags than the leading brands
- Dispenses like a tissue, cleans like a cloth
- Easy dispensing and tough texture for the ultimate wipes experience

Cleaning Advice? Visit [www.mrclean.com](http://www.mrclean.com)

CONTAINS NO PHOSPHATE



### **Lonza Disinfectant Wipes:**

- deliver non-acid disinfectant and cleaning performance
- (are a heavy duty disinfectant cleaner that) cleans, disinfects and deodorizes in one labor saving step.
- deodorizes by killing microorganisms (bacteria) that cause offensive odors.
- (improves labor results by) effectively controls (controlling) malodors.
- will disinfect, clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- is a complete, chemically balanced disinfectant
- will not leave grit or soap scum.
- is a (one-step) disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed.
- is a proven "one-step" disinfectant - cleaner which is effective the presence of 5% serum contamination.
- (Kills) (eliminates) (kitchen) (bathroom) (household) bacteria.
- (Kills) (eliminates) common household bacteria.
- Starts killing (bacteria) on contact
- Kills (eliminates) bacteria
- help you accomplish things you never thought a wipe could do
- (wipes) (cloths) (sheets) help you to accomplish things you never thought a wipe could do
- (help) take the hassle out of dispensing disinfecting wipes. The Easy-Glide Lid dispenses wipes one-at-a-time, like a tissue-box, so you get the number of wipes you want with no pinched fingers, (torn wipes), (or) (jammed lids). Plus they kill bacteria to keep your (family's) home (clean) ( ). Use it on bathroom and kitchen surfaces like countertops, appliances, door handles, light switches, toilets, sinks, and tubs.
- are designed for your toughest tasks. They are (thick and strong) (thicker and stronger) than regular wipes\*\* to stand up to (tough) (your toughest) messes, and they have a cloth-like texture for extra scrubbing power. Plus they kill bacteria to (help) keep your (family's) (home) (clean) ( ). (Try it) (Them) on (your) (tough) (toughest) messes in the kitchen and bathroom, like baked-on grease on your stove (top), sticky messes on your counters, and built-up grime on your bathroom sinks.

\*\*Versus (Insert other company's name or same company's brand name) Wipes

Cross-contamination is of major (housekeeping) concern. **Lonza Disinfectant Wipes** have been formulated to aid in the reduction of cross-contamination in the home, schools, institutions and industry.

### **Use Lonza Disinfectant Wipes:**

- in federally inspected Meat & Poultry Plants as a disinfectant on all surfaces in inedible product processing areas, non-processing areas and / or exterior areas..
- as a disinfectant on hard, nonporous surfaces.
- in kitchens, bathrooms and other household areas.
- to clean and disinfect finished floors, sinks and tubs.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and exterior toilet bowl surfaces.

**Lonza Disinfectant Wipes** are a one-step disinfectant and Bactericidal according to the current AOAC Use-Dilution Test Method modified in the presence of 5% organic serum against:

or

**Lonza Disinfectant Wipes** are effective against:

Staphylococcus aureus (Staph)  
Salmonella choleraesuis (Salmonella)  
Pseudomonas aeruginosa [Pseudomonas]  
Campylobacter jejuni [Campylobacter]

(Note to reviewer: The following is considered optional marketing language:)

**(AREAS OF USE:)**

Use Lonza Disinfectant Wipes in:

Bathrooms  
Children's room  
Homes (households)  
Kitchens  
Living room

Dental offices  
Hospitals  
Medical Offices  
Nursing homes

Day care centers  
Nurseries

Bars  
Cafeterias  
Convenience stores  
Food processing plants  
Food storage areas  
Institutional kitchens  
Restaurants  
USDA inspected food processing facilities

Athletic facilities  
Barber shops  
Business and office buildings  
Colleges  
Correctional facilities  
Dressing rooms  
Exercise facilities  
Factories  
Family Rooms (Dens)  
Health clubs  
Hotels  
Institutional facilities  
Institutions  
Laundry rooms  
Locker rooms  
Motels  
Playrooms  
Prisons  
Public facilities  
Public rest rooms  
Salons  
Schools  
Shower and bath areas  
Sick rooms

Camp grounds  
Play ground equipment

Airplanes  
Airports  
Boats  
Buses  
Campers  
Cars  
Emergency vehicles  
Mobile homes  
Ships  
Taxis  
Trailers  
Trains  
Transportation terminals

**(TYPES OF SURFACES:)**

Use Lonza Disinfectant Wipes on washable hard, nonporous surfaces of:

Appliances  
Bathroom fixtures  
Bathtubs [Fiberglass]  
Cabinets  
Cages  
Car seat  
Chairs  
Computer keyboards  
Counters (countertops)  
Cupboards  
Desks  
Diaper changing (tables)(counters)  
Diaper pails  
Doorknobs  
Faucets  
Floors  
Finished floors  
Garbage cans  
Glass  
Highchairs  
Linoleum  
Light switches  
Laminate flooring (such as Pergo®)  
Microwave ovens (exteriors)  
Non-Wooden Outdoor (patio) furniture except cushions and wood frames  
Refrigerators (exteriors)  
Refrigerated storage and display equipment  
Sealed floors  
Showers

Shower stalls  
Sinks (bathroom, kitchen)  
Storage areas  
Stoves (stovetops)  
Tables, (picnic tables)  
Telephones  
Exterior Toilet bowl surfaces  
Toilet seats  
Toys\*\*\*  
Tubs  
Tiles, glazed  
Walls

Non-critical medical device surfaces:

Beds [Medical] [Hospital]  
Bed frames  
Bed rails  
Crutches  
Non-critical [hospital] [medical] equipment surfaces  
[Medical] Examining tables  
[Medical] [Hospital] Lamps  
[Medical] [Hospital] Scales  
Stands  
Stethoscopes  
Walkers  
Wheel chairs

**Other hard nonporous surfaces made of:**

Acrylic  
Finished woodwork  
Formica®  
Glass  
Glazed ceramic  
Glazed enameled surfaces  
Glazed porcelain  
Metal  
Plastic (such as polystyrene or polypropylene)  
Sealed granite  
Sealed marble  
Sealed quartz  
Sealed stone  
Stainless steel  
Upholstery- vinyl and plastic

Note; Not recommended for unpainted wood, natural marble or brass.

\*\*\*Rinse toys with clean, potable water after disinfecting.



*(For canister)*

**To Open Package:**

Remove cover. Pull up (towelette) (wipe) (cloth) corner from center of roll. Thread through hole in the cover. Replace cover. Open center cap on cover to remove wipe. When not in use (When not using), close center cap (securely) to prevent moisture loss.

or

*(For carton or tub)*

**To Open Package:** Open cover and slowly peel back label on pouch. Remove (Pull out) (wipe) (towelette) (cloth) as needed. To retain moisture, reseal (pouch) (bag) by firmly pressing seal back on the (pouch) (bag) and close (carton or tub) cover.

or

*(For refill, pouch or bag:)*

**To Open Package:**

(Slowly) peel back the label (open seal). Remove (Pull out) (wipe) (towelette) (cloth) as needed. To retain moisture, reseal (pouch) (bag) by firmly pressing seal back on the (pouch) (bag)

or

*(for the Travel Pack size):*

**To Open Package:** Slowly peel back label. (Pull out) (Remove) (wipes) (towelettes) (cloths) as needed. Reseal label to retain moisture.

or

**To Open Package:** Open ziplock (Tear edge of pack). (Pull out) (Remove) (wipes) (towelettes) (cloths) as needed. Reseal ziplock to retain moisture.

or

*(for the single cloth sample pack):*

**To Open Package:** Tear edge of pack. (Pull out) (Remove) (wipes) (towelettes) (cloths).

or

**To Open Package:** (Remove package seal(s)) (Remove safety seal(s)) (Flip) Open lid. To remove first wipe (sheet) (wet cloth) (cloth) pull up on wipe and remove wipe through (dispensing) opening (wavy dispensing opening) (orifice). (The next wipe will pop up automatically). (Always) close (snap) lid securely between uses (to retain moisture).

or

**To Open Package:** (Remove package seal(s)) (Remove safety seal(s)). Open (Flip open lid (package)). To start (remove) (first) wipe (sheet) (wet cloth) take the edge of wipe from large opening to the small dispensing opening and pull up. (The next wipe (sheet) (wet cloth) (cloth) will pop up automatically.) (Always) close (snap) lid securely between uses (to retain moisture).

or

**To Open Package:** Open Lid. To start wipes, pull up on wipe and move wipe into the small dispensing opening (orifice) (aperture) (hole) (wave) and (pull sheet up to remove wipe) remove wipe. (The next wipe (sheet) (wet cloth) will pop up automatically). (Always) close (snap) lid securely between uses (to retain moisture).

### **DIRECTIONS FOR USE:**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### **TO CLEAN AND DEODORIZE:**

Wipe surface with (wipe) (towelette) (cloth) (sheet). Let air dry. Discard used (wipe) (towelette) (cloth) (sheet) in trash. Do not flush in toilet.

#### **TO CLEAN AND DISINFECT:**

Wipe (hard, nonporous) surface with (wipe) (towelette) (cloth) (sheet) until surface is visibly wet. Allow surface to remain wet for 10 minutes. Let air dry. If surfaces are extremely dirty, clean first with another (wipe) (towelette) (cloth) (sheet) before disinfecting.

Discard used (wipe) (towelette) (cloth) (sheet) in trash. Do not flush (in toilet).

Rinse food contact surfaces with clean, potable water after disinfecting. Do not use to disinfect dishes, glassware or utensils.

Do not use as a diaper wipe or for personal cleansing.

(Note: Not recommended for unpainted wood, natural marble or brass.)

### **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Caution. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

#### **FIRST AID**

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

#### **STORAGE AND DISPOSAL:**

Store product in original container in areas inaccessible to children. Keep securely closed. (Reuse) (Refill) empty container only with Lonza Disinfectant Wipes (refills). (If not refilling,) Discard empty container in trash or recycle (if available).

Questions?

Comments?

Call (Insert phone number)